

REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

The Office Action:

- a) rejected claims 9 and 10 under 35 USC §112, Second Paragraph, as being allegedly indefinite; and
- b) rejected claims 1 – 22 under 35 USC §103(a) as being allegedly being unpatentable over United States Patent No. 5,658,919 to Ratnaraj et al. ("Ratnaraj") in view of United States Patent No. 5,759,579 to Singh, et al. ("Singh") and United States Patent No. 5,055,306 to Barry et al. ("Barry").

In view of the amendment to claims 9 and 10, in which each claim was amended to depend from claim 6 instead of claim 5, Applicants respectfully submit that the rejection of these claims under 35 USC §112, Second Paragraph, has been overcome and should be withdrawn.

Claims 1 – 22 remain pending in this application after entry of this amendment.

I. The Rejection of Claim 1 - 22 As Being Unpatentable Over Ratnaraj in view of Singh and Barry under 35 USC §103(a) Should Be Withdrawn

Claims 1 - 22 stand rejected under 35 USC §103(a) as allegedly being unpatentable over Ratnaraj in view of Singh and Barry. Applicants respectfully disagree for the reasons that follow.

According to the Office Action, Ratnaraj discloses an acetaminophen suspension system in which the suspended acetaminophen particles "are not coated with a controlled release formulation." Singh also discloses a pharmaceutical suspension system in which the suspended particles are not coated with a controlled release composition. By contrast, the invention as presently claimed is directed to a "suspension... comprising: particles of an NSAID and/or acetaminophen, said particles being substantially covered with one layer of a controlled release composition..." (emphasis added).

Barry is directed to "granular sustained-release pharmaceutical formulations presented in the form of effervescent or water-dispersible tablets." Barry, column 1, lines 5 – 10. The granules of Barry have a coating comprising: 1) a water insoluble but water swellable acrylic polymer; and 2) a water soluble hydroxylated cellulose derivative. Barry, column 6, lines 32 – 36.

Applicants respectfully submit that the invention as presently claimed is clearly distinguishable from Barry. First, Barry is not directed to a "liquid suspension dosage form" as presently claimed, but rather is directed to tablet dosage forms. The Office Action failed to provide any motivation for combining a reference that discloses a coating suitable for use in tablet dosage forms with another reference that uses uncoated particles within a liquid suspension dosage form.

Second, *assuming arguendo* that such a combination of references was proper, Applicants further submit that one skilled in the art would readily appreciate that a liquid suspension dosage form having a "duration of therapeutic effect for at least about 8 hours" as claimed herein could not be prepared with particles having the coating of Barry as proposed by the Examiner. This is because the coating of Barry contains a water soluble hydroxylated cellulose derivative component that would dissolve when the coated particles are placed into the liquid vehicle of the liquid suspension dosage form. After the water soluble hydroxylated cellulose derivative coating is dissolved away from the particles, the active agent within the particle would thereby be available for immediate release prior to administration by a consumer.

Therefore, because the liquid suspension combination that would result from using the water soluble coating of Barry on the suspended particles of Ratnaraj or Singh would still not possess "a "duration of therapeutic effect for at least about 8 [or 12] hours" as required by the claims herein, Applicants respectfully submit that the rejection of the claims under 35 USC §103(a) as allegedly being anticipated by Ratnaraj in view of Singh and Barry has been overcome and must be withdrawn.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

In the event that all of the claims are not in condition for allowance, Applicants respectfully request for an interview with the Examiner before the preparation of the next Office Action.

Respectfully submitted,

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